

DAIDS Enterprise System (DAIDS-ES)

The DAIDS Enterprise System (DAIDS-ES) is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. Components of the DAIDS-ES that will be functional at the time of award include:

DAIDS Training Calendar

The DAIDS Training Calendar is an integrated MS-Outlook application to track DAIDS training events. The DAIDS Training Calendar has been developed in response to a need for an easy-to-use system to track and share information about training activities, including content, schedule, participants, travel requirements, registration policies, costs, etc.

DAIDS Master Contact System

The DAIDS Master Contact System is a centralized system for all address and contact information for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc.

DAIDS Expedited Adverse Event Reporting System (DAERS)

The DAERS is a web-based application for expedited reporting of adverse events in DAIDS sponsored clinical trials. DAERS is a 21 CFR Part 11 compliant system for use in therapeutic, vaccine and prevention trials.

DAIDS Protocol Management System

The DAIDS Protocol Management System supports end-to-end clinical trials processes, including: protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and closeout. The system is CDISC and HL7 compliant with full auditing capabilities.

Successful awardees shall, as needed: 1) interface with the DAIDS-ES to provide access to data in local system(s); 2) adapt data management system(s) to receive and store data from the DAIDS-ES; 3) integrate data systems to dynamically obtain data from the DAIDS-ES. All data exchange mechanisms shall be based on DAIDS-defined platform technology standards.

To achieve compatibility, DAIDS and its collaborators (contractors, cooperative agreement holders, grantees, etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis.

This requirement will include the need to utilize DAIDS-ES specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant applications that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES.

Depending upon the architecture and implementation of offeror data management system(s), the following activities may be required to be compatible with the DAIDS-ES.

Build Interface:

Using DAIDS-ES specified data standards, collaborators shall provide access to data in their local system(s). Standards shall either be industry data exchange standards such as those specified by NIH, CDISC, HL7 or adapted versions of these as defined by DAIDS.

System Adaptation:

Collaborators may need to adapt or modify their data management system(s) to receive and store data from the DAIDS-ES. For example, DAIDS is establishing a standardized naming and numbering convention for its awardee institutions. The DAIDS shall provide collaborators with a single set of institution or laboratory names and identifiers for all of its research participants. Collaborator's data system(s) may have to be adapted or modified to accommodate the DAIDS standard(s).

System Integration:

Collaborators may be required to dynamically obtain data from the DAIDS-ES to perform specific job functions. This will require the integration of collaborator's system(s) with the DAIDS-ES via data linkages using the appropriate latency factor or through Web Services. For example, the DAIDS-ES will serve as the central repository for investigator and protocol status information. Collaborator's whose work requires information from the DAIDS-ES must dynamically integrate it into their respective data system(s).